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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,798	12/12/2001	Valentin Kramer	31567.3	9144
5251 7590 05/11/2007 SHOOK, HARDY & BACON LLP INTELLECTUAL PROPERTY DEPARTMENT 2555 GRAND BLVD KANSAS CITY, MO 64108-2613			EXAMINER CHANG, VICTOR S	
		ART UNIT 1771		PAPER NUMBER
			MAIL DATE 05/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/017,798	KRAMER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Victor S. Chang	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 19 March 2007.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 19-22,24-27,32-34 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 19-22,24-27,32-34 and 37-42 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Introduction*

1. Applicants' amendments and remarks filed on 3/19/2007 have been entered. Claim 32 has been amended. Claims 19-22, 24-27, 32-34 and 37-42 are active.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 112*

3. Claims 19, 23-25 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For claim 19, the recitation "... a first plurality of fibrils interconnecting said first node with a said second node, said first plurality of fibrils defining a first group of pores therebetween, said **first group of pores** falling substantially with in a **first size range** ..." (emphasis added) appears to be vague and indefinite, because these terms are not defined in the specification and the basis of the structural limitation is Fig. 2, therefore it is unclear what the term "first size range" is referring to: "an *area* containing the first plurality of fibrils" or "a *pore size* range of the first group of pores"? Nevertheless, in accordance to the dependent claims 24 and 25, the term "first size range" is interpreted as "pore size range of the first group of pores" in the present Office action. Similarly, the term "second size range" is interpreted as "pore size range of the second group of pores". Clarifying claim language is requested.

***Rejections Based on Prior Art***

4. Claims 19-22, 24-27, 32-34 and 37-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Edwin et al. [US 6039755].

Edwin's invention relates to a tubular expanded polytetrafluoroethylene (ePTFE) microporous graft. The graft has a microstructure of nodes interconnected by fibrils. The nodes are elongated under radial expansion, and are substantially perpendicular to the longitudinal axis of the tubular ePTFE. The fibrils are oriented parallel to the longitudinal axis of the tubular ePTFE material [col. 2, lines 42-49; Figs. 1 and 2].

For claims 19-22, each of the micrographs in Figs. 18D, 21B or 21D shows the same local structural features as Fig. 2 of the present application, which has been stated by applicants as the basis of the recited structural features of claimed invention. Specifically, Edwin shows in the micrographs an expanded microporous ePTFE membrane having local regions in which there is a plurality of elongated and generally parallel large nodes, and small intermediate node between the large nodes. The large and small intermediate nodes are interconnected with a plurality of fibrils, which define different pore sizes in regions between the large/large nodes and large/small intermediate nodes. Edwin anticipates the instant invention as claimed. Regarding the limitation that the article is created from a mixture of a first resin and a second resin having a different molecular weight than said first resin, and then expanding said mixture, since any polymeric material inherently comprises a distribution of molecular weights, i.e., a mixture of molecules over a range of different molecular weights, Edwin's ePTFE anticipates the mixture of different weights as claimed.

For claims 24-27, Edwin shows in Fig. 18D that the lengths of fibrils for small pores in the range of 2-15 mm, and lengths of fibrils for large pores in the range of 20-50 mm.

For claims 32-34, Edwin's Figs. 18D, 21B or 21D read on the local structural features of instantly claimed invention as set forth above. The terms "first material" and "second material" in independent claim 32 are both read upon by Edwin's PTFE, because the term "material" lacks any limitation on composition and/or molecular structure. Even if different molecular weights are considered, since Edwin's polymeric PTFE material is inherently distributed over a range molecular weights, Edwin still anticipates the terms "first material" and "second material" as claimed. Regarding the limitation that the local structural features are repeated regularly and consistently throughout a substantial portion of the membrane, since applicants generally rely upon Fig. 2 for the local structural features between the nodes and fibrils [see reply filed 3/3/2005, page 3, and reply filed 10/27/2005, page 7], and Figs. 3 and 4 of present application provide an overall structural features of the mosaic pattern, the term "regularly and consistently throughout a substantial portion" is interpreted as the overall mosaic pattern shown in Figs. 3 and 4 (i.e., the intermediate node is present in substantial pairs of large nodes, but not between every pair of large nodes), and is clearly read upon by the same overall mosaic pattern shown in Edwin's Figs. 18C, 21A or 21C (Figs. 18D, 21B or 21D are magnified local regions in Figs. 18C, 21A or 21C). Finally, regarding the use limitation for blood contact application, since statements of intended use do not serve to distinguish structure over the prior art, it has not been given any patentable weight. See *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974).

For claims 37-42, since they claim the same scope of limitations of claims 19-22, 24-27 and 32-34, they are also rejected as set forth above.

***Response to Amendment***

5. Applicants agree at Remarks page 6 that the term “size range” in claim 19 refers to the size range of the pores. However, since the term “size range” is not defined in the original specification, the examiner maintains that clarifying claim language is required in the next reply. While the scope of this term is defined in dependent claims 24 and 25, the term is not defined in independent claim 19, and therefore renders the language vague and indefinite.

Applicants argue at pages 6-7, bridging paragraph, that the statutory basis for the rejection appears to be 102(e). However, a careful review of the dates of prior art and the priority claim of the instant invention, the examiner corrects the basis as under 102(a). The examiner apologizes for this inadvertent error.

Applicants argue at pages 7-10 that Edwin’s claim language is limited to “substantially retaining an average internodal difference throughout the radially deformed tubular structure”, whereas claim 19 contains limitations not present in Edwin, because the instant invention claims an intermediate node connected to the first and second nodes by relatively short fibrils, as shown in Fig. 2 of instant invention. However, while Edwin discloses additional embodiments not relied upon, the relied upon disclosures by Edwin read on the instant invention as claimed. Since each of the micrographs in Figs. 18D, 21B or 21D shows the same local structural features as Fig. 2 of the present application, applicants’ arguments directed to Edwin’s additional embodiments not relied upon are misplaced and unpersuasive.

Applicants argue at pages 10-11, bridging paragraph, that Figs. 18D, 21B and 21D do not show a repeated structure-within-a-structure arrangement, nor any consistent pattern of discretely-sized pores that is repeated. Applicants further argue that the Edwin's pores are radically oriented in these figures, and are not part of any identifiably distinct arrangement recited in claim 19 of instant invention. However, Figs. 18D, 21B and 21D do show the local structural features as claimed, and Figs. 18C, 21A and 21C read upon the over mosaic pattern having the local features repeated throughout a substantial portion of the membrane. Further, the connecting fibrils among the nodes are generally in the same orientation as illustrated in Fig. 2 of instant invention, i.e., applicants appear arguing against their own illustration and micrographs.

Applicants argue at page 11 that the examiner has not made a record as to why the recited pore ranges are met. However, the examiner has pointed out that Edwin shows in Fig. 18D lengths of fibrils for small pores in the range of 2-15 mm, and lengths of fibrils for large pores in the range of 20-50 mm.

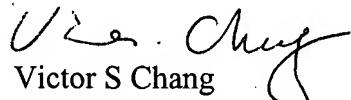
Applicants argue at page 12 that claim 32 requires a composition of two different materials. However, the claim merely recites "first material" and "second material", there is no requirement that they are different in composition, nor in molecular weights.

### *Conclusion*

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Victor S Chang  
Examiner  
Art Unit 1771

5/7/2007